REMARKS

A. Status of Claims

Claims 101-108 have been renumbered as claims 100-107 to correct an error in claim numbering.

Claims 1-4, 6, 11, 74-95, and 97-107 are pending.

Claims 3, 6 and 80 have been amended without prejudice or admission. Support for these amendments can be found, e.g., in paragraph [0044] of the application as filed.

It is respectfully submitted that no new matter has been added by virtue of the present amendments.

Claims 3, 6, 74-80, 82, 84, 86, 88, 90-95, and 97-107 are encompassed by the elected invention.

B. Claim Rejections- 35 U.S.C. § 103

Claims 3, 6, 74-80, 82, 84, 86, 88, 90-95, and 97-107 were rejected under 35 U.S.C. § 103(a) over the combination of U.S. Patent No. 5,419,920 to Masson et al. ("the '920 patent") and U.S. Patent No. 5,494,681 to Cuca et al. ("the '681 patent").

The rejection is respectfully traversed.

The Examiner states on page 4 of the Office Action that "[t]he '920 patent establishes the level of skill in the art regarding imparting a traceable scent to a polymeric film" and on page 3 of the Office Action that in the '920 patent "[t]he scent is absorbed into a substrate such as film, fiber or sponge, where the substrate is a polyolefin such as polyethylene." In response, Applicant respectfully submits that polyethylene is "a plastic polymer of ethylene" used in

"manufacture of containers, packaging, and electrical insulation." See Appendix A. "Polyethylene" is not listed in the Handbook of Pharmaceutically Excipients (i.e., Handbook of Pharmaceutically Excipients, fourth edition, published by the Pharmaceutical Press and the American Pharmaceutical Association). See Appendix B. The '920 patent does not provide a reason for the skilled person to impart a traceable scent of polyethylene to a pharmaceutical dosage form to provide information about the pharmaceutical dosage form or establish the level of skill in the art regarding imparting a traceable scent to a **pharmaceutical dosage form**. In fact, the '920 patent lacks a disclosure of any pharmaceutical dosage forms, any suggestion that the "markers" described therein are suitable for incorporation into pharmaceutical dosage forms, and any methods for providing for identification of pharmaceutical dosage forms.

In response to the Examiner's statement on page 2 of the Office Action that "[t]he '920 [patent] discloses a method of imparting a scent or scent profile to an object and further detecting that scent at a later time," Applicant respectfully notes that the '920 patent does not describe any pharmaceutical dosage forms. Rather, the objects of the '920 patent include, e.g., "art objects, precious items, and collectible items." See column 1, lines 10-12. The objects explicitly mentioned in the '920 patent are "tapestries and carpets; books, stamps and paintings; furs and leathers; and furniture" and "metal objects, such as articles made of gold, or objects made of oxides or silicoaluminates such as ceramics, glassware and precious and semiprecious stones." See column 4, lines 11-23.

For the same reasons and contrary to the Examiner's assertion on page 3 of the Office Action, it would not have been obvious from the disclosure of the cited references "to track [sic; track] and identify the dosage form of the '681 patent by the method of the '920 patent in order to keep track of schedule I or II substances from a distance." In fact, the phrase "schedule I or II substances" is not even mentioned in the cited references.

Applicant respectfully disagrees with the Examiner's assertion on page 3 of the Office Action that "[t]he specific flavors of the '681 patent" would meet the limitations of the instant claims. There is no description in the '681 patent of its flavors indicating or that "the dosage form is authentic" as recited in instant claims 3, 6, 80, and 84. There is also no description in the

'681 patent of its flavors indicating "when and/or where the pharmaceutical dosage form was manufactured, bottled or packaged" as recited in instant claim 3. At least for these reasons, the flavors of the '681 patent do not meet the limitation of the scents or scent profiles recited in instant claims 3, 6, 80, and 84.

Applicant also respectfully disagrees with the Examiner's assertion on page 4 of the Office Action that "it would be obvious to apply different flavors to different batches in order to tell them apart after manufacture," as there is no description in any of the cited references of using different flavors in different batches of pharmaceutical dosage forms.

With further regard to independent claims 3 and 6, Applicant respectfully submits that the combination of the cited references does not teach or suggest "associating the scent or scent profile" with the identity or source of the pharmaceutical dosage form as recited in these claims. In response to the Examiner's statement on page 3 of the Office Action that "the instant claims do not recite an active step of 'authenticating' the dosage form, but only 'allowing' for the dosage form to be authenticated," Applicant respectfully notes that the phrase "allowing for an authentication of the dosage form" has been deleted from claims 3 and 6. Claims 3 and 6 each independently recites "associating the scent or scent profile."

In conclusion, Applicant respectfully submits that obviousness requires more than a mere showing that the prior art includes separate references covering each separate limitation in a claim under examination. KSR at 418. Rather, obviousness requires the additional showing that a person of ordinary skill in the art at the time of the invention would have selected and combined those prior art elements in the normal course of research and development to yield the claimed invention. *Id.* at 421; *see also Bayer Schering Pharm. AG v. Barr Labs., Inc.,* 575 F3d 1341, 1350 (Fed. Cir. 2009) (Newman, J., dissenting) ("The statutory criterion is whether the invention would have been obvious to persons of ordinary skill at the time of the invention, not whether it is sufficiently simple to appear obvious to judges after the discovery is finally made…").

Here, the Examiner has failed to show that the combination of the cited references

teaches or suggests each and every element of the instant claims. The Examiner has also failed to make the the additional showing of why a person of ordinary skill of the art would pick and choose among the disparate elements set out in the cited references and to combine them to arrive at the invention **as claimed.**

Applicant respectfully reiterates that there is simply no connection between the '920 patent and the '681 patent. The '920 patent is neither concerned nor is not reasonably pertinent to the taste-masked pharmaceutical materials described in the '681 patent. The skilled person would therefore not have had any reasons to combine the '920 patent and the '681 patent, let alone use the method described in the '920 patent to impart a scent or scent profile to a pharmaceutical dosage form comprising an active agent during manufacture of the dosage form to provide information about the dosage form as recited in claims 3, 6, 80, and 84. The Examiner has thus failed to demonstrate the claimed invention is obvious **as a whole**.

For all of the foregoing reasons, and the reasons presented in the response filed on October 17, 2011, herein incorporated by reference, reconsideration and withdrawal of the rejection is respectfully requested.

CONCLUSION

An allowance of the present application is earnestly solicited. According to currently recommended Patent Office policy, the Examiner is specifically authorized to contact the undersigned by telephone in the event that a telephonic interview will advance the prosecution of this application.

Respectfully submitted,
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